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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,652	11/27/2001	Bernard Klein	USB 98BEIDMPOI	5268

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/890,652

Applicant(s)

BERNARD KLEIN

Examiner

Michail A Belyavskiy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Applicant's amendment, filed on 11/27/01 (Paper No. 5), is acknowledged.  
Claim 3,4,6,10,11,13-16 has been amended.  
Claim 17-19 has been added.

*Claims 1-19 are pending and being acted upon presently*

### Election/Restrictions

In the interest of compact prosecution:

2. The following is noted:

A. Claim 16 is subject to rejection under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e. results in a claim which is not a proper process claim under 35 U.S.C 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App.1967) and Clinical Products, Ltd v Brenner, 255 F Supp.131,149 USPQ 475 (D.D.C. 1966).

For examination purposes, "use" claims are prosecuted as "methods of use"

B. It is also noted, that Claim 16 encompass "methods of use" of the cell composition for :

- i) preparation of drugs,
- ii) restoration of hematopoiesis,
- iii) protection of patients against infectious diseases, or
- iv) protection of patients against residual tumors.

Claimed methods of use appear to target separate and distinct targets , differ with respect to ingredients, method steps, and endpoints therefore, each method is patentably distinct.

Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

C. In order to avoid rejection under 35 USC 112 2<sup>nd</sup> paragraph applicant is invited to amend the method and process claims to set forth clear, distinct and positive process steps with a step (or lacks a resolution or correlating step) that clearly relates to the preamble of the claim(s).

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D. Applicant should amend the recitation of Claim 9 for indefiniteness as a result of the misspelling of "thrombopoietin", and the improper nomenclature of "FLAT-3 ligand" and "c-kit" as well as "IL-3" and "IL-6". Applicant should clarify the intent of "FLAT-3 ligand".

Applicant is invited to amend the recitation of claim to include Markush language if appropriate.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 3, 13-15, drawn to cell composition and pharmaceutical composition containing macrophages.

Group II, claims 2, 4, 5, 6, 17-19 drawn to cell composition and pharmaceutical composition containing macrophages, myeloid cells and progenitor cells

Group III, claims 7-12 drawn to a process for preparation of a cell composition.

Group IV, claim 16, drawn to methods of use of the cell composition for preparation of drugs.

Group V, claim 16, drawn to methods of use of the cell composition for restoration of hematopoiesis.

Group VI, claim 16, drawn to methods of use of the cell composition for protection of patients against infectious diseases.

Group VII, claim 16, drawn to methods of use of the cell composition for protection of patients against residual tumors.

4. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was found in the International Search Report, the Invention Group I was found to have no special technical feature that defined the contribution over the prior art of Srour ( US Patent No 5,672,346) (see entire document).

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Srouer discloses human pluripotent hematopoietic stem cell enriched composition and their capacity to differentiate into members of erythroid, myeloid and megakaryocyte cell lineages. By grafting human hematopoietic cells in a mammal, peripheral blood cell compositions containing CD14+ cells (macrophages) can be obtained.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

### **Species Election**

5. This application contains claims directed to the following patentably distinct species of the claimed Invention III: wherein coculture is carried out in the presence of cytokines, growth factors or their agonists, recited in the claim 9

These species are distinct because their structure, physicochemical properties and mode of action are different

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

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7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
Technology Center 1600  
April 15, 2002

*Phillip Gambel*  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
*TC 1600*  
*4/16/02*